DETAILED ACTION

Status of Claims

1. Claims 1, 29, and 34-41 are pending in this application.

2. Claims 1, 29, and 34-41 are examined.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Applicant's arguments, see pages 25-27, filed 8/14/09, with respect to the rejection(s) of claim(s) 1, 29, and 34-41 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Muto et al as delineated below.

5. Claims 1, 29, and 34-41 are rejected under 35 U.S.C. 103(a) as being obvious over Muto et al (US 2004/0259877).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject

matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The claimed invention is drawn to a method for therapeutic treatment of skin cancer, melanoma, lung cancer, liver cancer, breast cancer, pancreatic cancer, acute myeloblastic leukemia, multiple myeloma, Lennert's lymphoma, T-cell leukemia, rhabdomyoma, fibrosarcoma, or neuroblastoma in a mammal, which comprises administering to a mammal a therapeutically effective amount of a compound represented by the general formula (I) or a pharmacologically acceptable salt thereof, wherein formula (I) is defined as specified in claim 1 (see claim 1). The mammal may be a human (claim 29). Claims 34-41 further limit the substituents of formula (I). Applicants have elected lung cancer as the cancer to be treated and Compound No. 4 (page 63 of specification) as the compound of general formula (I).

Muto et al teach inhibitors against the production and release of inflammatory cytokines, represented by the general formula (I) (abstract). The compounds are useful for treating diseases including lung cancer (paragraph 72). Muto et al exemplify the

compound which corresponds to Compound No. 4 of the claimed invention (see Compound No. 50, page 47).

Muto et al do not specifically teach the use of the compound corresponding to Compound No. 4 for the treatment of lung cancer.

However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to select the compound for the treatment of lung cancer; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because Muto et al fairly teach and suggest that the medicaments may be used for the therapeutic treatment of cancers including lung cancer, and exemplify the elected compound.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. **Claims 1, 29, and 34-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 17, 21, and 24-33 of copending U.S. Patent Application No. 10/564,407 (appl. '407).**

Claim 17 of copending appl. '407 is directed towards a medicament for preventive treatment of dermal pigmentation and/or development of skin cancer, which comprises as an active ingredient a substance selected from the group consisting of a compound represented by the below general formula (I) wherein E represents a 2,5-bis(trifluoromethyl)phenyl group or a 3, 5-bis(trifluoromethyl)phenyl group and Rz represents a halogen atom (see claim 17). Unlike the instant claims, the reference claims are limited in scope to a method for preventive treatment of dermal conditions.

It would have been obvious to a person of skill in the art at the time the invention was made to treat a patient with any suitable cancer with the reference method comprising administering the identical compounds as recited in the instant claims for its anti-tumor effect. One would have been motivated to treat any cancer with said reference method because one would reasonably expect that administration of the same drug to the same (cancer) population would have the therapeutic effects. Thus, a person of skill in the art at the time the invention was made would have considered the instant claimed invention to be an obvious variant of the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Response to Arguments

8. Applicant's request to allow the present application (the earlier filed application) to proceed to issuance, whereby an obviousness-type double patenting rejection can be made (if appropriate) in the copending application is duly noted; however, since the instant claims have not been found to be allowable, the provisional rejection is maintained for reasons of record.

9. Claims 1, 29, and 34-41 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 19, 26-30, and 55-63 of copending US Patent Application No. 10/433,619.

Copending application '619 claims a method of inhibiting activation of NF-kB comprising administering the identical instantly claimed compounds of formula 1 (claim 1) and a method for therapeutic treatment of a disease caused by NF-kB activation in a mammal comprising administering a compound represented by the formula (I) (claim 59). The disclosure of copending application '619 defines said diseases to include numerous cancers, including lung cancer (paragraphs 71 and 72). Therefore, the claims are drawn to the same subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims of the copending applications have not in fact been patented.

Response to Arguments

10. Applicant's arguments with respect to the Callahan et al reference have been considered but are deemed moot since the Callahan et al reference is no longer a part of the rejection.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
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